



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0264]

Draft Guidance for Industry on Chronic Fatigue Syndrome/Myalgic Encephalomyelitis:

Developing Drug Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.” The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet Maynard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3185, Silver Spring, MD 20993-0002, 301-796-2300.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.” The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of CFS/ME.

Currently, there are no approved therapies indicated to treat CFS/ME. The lack of approved therapies indicated for the treatment of CFS/ME represents a public health concern. To foster drug development in CFS/ME, this draft guidance outlines the following key issues in drug development in CFS/ME:

- The case definitions or criteria for CFS/ME that could be used to define a patient population in the context of drug development
- Recommendations for establishing efficacy in CFS/ME based on patient-reported symptoms and measurements of exercise capacity
- Recommended trial design and duration

- Recommendations for establishing safety in CFS/ME

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drug products for the treatment of CFS/ME. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001.

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-05189 Filed 03/10/2014 at 8:45 am; Publication Date: 03/11/2014]